

Message

From: Burke, Thomas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FFC3DD34EA495B9A31E61B778FBBEC-BURKE, THOM]
Sent: 9/9/2016 2:15:07 PM
To: Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]
CC: Deener, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]; Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcfb4c5bbc39c666fee31ec3-Bahadori, Tina]; Kavlock, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eebac67f01094409a7fdaa955a837884-Kavlock, Robert]; Ross, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98359cd1f66f46ec91d327e99a3c6909-Ross, Mary]; Gwinn, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bdc5237a5c440a7b664518e23eb5647-Gwinn, Maureen]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Slimak, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=197d6551afaf4d90b087c4d5bf62b53c-Slimak, Mike]; Thomas, Russell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12f119e7a3ee447499f3d6ab5d20daeb-Thomas, Rus]; Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]
Subject: Re: Why words might matter: Advocates Warn EPA 'Fit For Purpose' Risk Reviews Could Violate TSCA

Looking forward to our next discussion. Some very supportive statements on tiered approach during the recent BEST meeting.

Tom

Sent from my iPhone

On Sep 9, 2016, at 9:04 AM, Vandenberg, John <Vandenberg.John@epa.gov> wrote:

Deliberative Process / Ex. 5

<https://www.nap.edu/read/2125/chapter/26>

From: Deener, Kathleen
Sent: Thursday, September 08, 2016 7:20 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Burke, Thomas <Burke.Thomas@epa.gov>; Kavlock, Robert <Kavlock.Robert@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>; Vandenberg, John

<Vandenberg.John@epa.gov>

Subject: Re: Why words might matter: Advocates Warn EPA 'Fit For Purpose' Risk Reviews Could Violate TSCA

Very interesting read. Thanks Tina.

Sent from my iPhone

On Sep 8, 2016, at 6:47 PM, Bahadori, Tina <Bahadori.Tina@epa.gov> wrote:

Advocates Warn EPA 'Fit For Purpose' Risk Reviews Could Violate TSCA

September 07, 2016

Environmentalists are cautioning that one EPA toxics officials' remarks that the agency is considering "fit for purpose" chemical risk reviews under the revised Toxic Substances Control Act (TSCA) -- in which EPA would target a review to inform regulatory decisions rather than a broader general assessment -- could violate the law.

"Nowhere in the extensively revised TSCA does Congress use the term 'fit for purpose' to describe the risk evaluations it wants EPA to undertake," say joint Aug. 24 comments filed by several environmental groups on EPA's rule for developing a process to conduct risk evaluations under the updated law.

EPA has used the term "fit for purpose" for previous work, for example in a July 2012 draft "Framework for Human Health Risk Assessment to Inform Decision Making" released by the Office of the Science Advisor, in which the agency described it as the "consideration of the usefulness of the assessment for its intended purpose, to ensure that the assessment produced is suitable and useful for informing the needed decisions."

But the environmentalists in their written comments warn that EPA would be violating TSCA if it focused risk reviews based on how useful they would be to inform potential regulation of chemicals, rather than a general review of a substance's risks. *Relevant documents are available on InsideEPA.com. (Doc. ID: 194300)*

The groups -- Earthjustice, BlueGreenAlliance, Breast Cancer Action Fund, Center for Biological Diversity, Greenpeace, and others -- refer to an Aug. 9 presentation by Tala Henry, director of

the agency's risk assessment division within its Office of Pollution Prevention & Toxics at a Washington, D.C. meeting. At that meeting, Henry indicated that the agency intends to conduct "fit for purpose" risk evaluations, according to the comments.

EPA sought public comment at the recent meeting and through a docket open for input until Aug. 24 on a rule it will develop on its process for conducting risk evaluations to determine whether a chemical "presents an unreasonable risk of injury to health or the environment" under section 6 of the law. The section outlines requirements on chemical reviews and how chemicals should be prioritized to undergo those reviews. EPA has one year from the statute's June 22 implementation date to craft the rules on prioritizing substances and evaluating them.

Henry also indicated that as part of the TSCA work plan risk assessment program, staff have begun to transition from a more specific scoping exercise, where assessments looked only a few narrow uses of a chemical. The work plan effort was as designed to focus the efforts of its program to address risks from chemicals using authority under the existing TSCA, though the revised TSCA bolsters the agency's power to regulate substances.

EPA's Aug. 9 presentation says that EPA plans to in its risk evaluations to examine the ways chemical-specific uses affect exposure pathways, routes, and potentially exposed populations.

But the environmental groups in their letter say TSCA Section 6(b)(4)(F), which describes risk evaluation requirements under the new law, does not allow a "fit for purpose" approach.

They cite a later 2014 version of the agency's draft "Framework for Human Health Risk Assessment to Inform Decisionmaking," which indicates that the "fit for purpose" approach involves targeting risk evaluations toward risk management options. "TSCA envisions that EPA will design and conduct risk evaluations to identify and characterize risks with an open mind to what the data will show, and then determine the appropriate risk management -- not to design a risk evaluation with particular risk management options in mind," the comments say.

Environmentalists are also urging EPA to reject industry's bid for a "tiered" evaluation process for chemical reviews

consisting of an initial "screening level assessment," followed by a more in-depth risk evaluation, with different types of data appropriate to different tiers.

"We strongly urge EPA to reject the notion that tiered risk evaluation is even permitted under TSCA, let alone required," the groups say in their comment letter, adding, "Congress would have explicitly required EPA to conduct tiered risk evaluations if it had wanted EPA to adopt this practice."

Moreover, the groups say, if Congress intended EPA to develop a tiered process under section 6 of the new law for targeting existing chemicals, it would not have made specific references to tiered testing requirements under section 5, which governs chemical safety testing and data generation.

In developing the rule, EPA is seeking input on how to implement a directive in the revised TSCA for using either "sentinel" or "aggregate" exposures to evaluate chemicals, the latter being the approach advocates favor, saying it would better reflect real world risk compared to the sentinel method traditionally used by agencies.

Section 6(b)(4)(f) says that evaluations shall "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration."

Environmentalists say that sentinel exposures are in line with EPA's traditional approach for risk assessment, taking the most serious risk and assuming that reducing that exposure will lower overall risk and that this is the chemical sector's preferred approach, unlike the aggregate exposures environmentalists prefer. Aggregate exposure assesses every possible exposure and leads to an evaluation that aims to reduce the sum total of risk. EPA speakers, however, said that they had little knowledge of the sentinel concept and are hoping for comments on it to further elucidate the approach.

Jeff Morris, deputy director of EPA's Office of Pollution Prevention and Toxics (OPPT), said at the Aug. 9 meeting that, "Sentinel exposures, is one that we would like comment on," adding that,

"It's not a term we've typically used in our program but it is used in other areas, such as occupational exposure risk assessment."

In their comments, the environmental groups say that the provision should not be read to mandate any particular exposure assessment technique. Rather, they say, it mandates that EPA "describe whether" it applied particular exposure techniques. "EPA's regulations and/or guidelines should clearly state that 'sentinel exposures' is never a replacement for aggregate exposure assessment under TSCA," they say.

Aggregate assessment must be considered as a requisite component of using the best available science, a requirement under section 26 governing the general administration of the statute, the groups argue.

Chemical industry groups, however, continue to seek a tiered approach to risk evaluation, with the American Chemistry Council (ACC) saying in its Aug. 24 comments, "We believe the statute contemplates a tiered approach to risk evaluation and recommend that EPA include a tiered approach in the rule."

The group says that because the law allows for up to six months in between when EPA designates a chemical a "high-priority substance" and when the agency must publish the scope of the risk evaluation, EPA could use the scoping phase to conduct a screening level review. "A tiered approach, where EPA uses the scoping step (step 1) to conduct a quantitative screening level analysis, will allow EPA to focus its limited resources on more robust refined risk evaluations for only those conditions of use where unreasonable risks cannot be ruled out," ACC says in its comments.

The first phase of the evaluation would require less data and be based on conservative, health protective assumptions. EPA could then do a second, more refined evaluation requiring more realistic and representative data, higher tier modeling approaches, and a more comprehensive consideration of human relevance and dose-response relationships, for chemicals it believes should receive further consideration.

On sentinel exposures, the group says, "We believe EPA should include definitions of both aggregate and sentinel exposures in

the proposed regulation so the regulated community will understand how EPA intends to apply the terms, and to ensure consistency and regularity in application."

While ACC recognizes that EPA need not apply both types of exposure assessment, the group argues the statute gives EPA the discretion to do so and that sentinel exposure "should be thought of as the exposure that is judged to cause the plausible upper-bound individual human exposure to a substance of interest within a broad category." -- *Bridget DiCosmo*

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